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TITLE: In-Home Exposure Therapy for Veterans with PTSD

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14. ABSTRACT We have set up a study that will provide a certain type of exposure therapy, called prolonged exposure therapy (PE) to military Veterans. We will ask 272 Veterans to participate in the study. Our goal is to compare PE conducted in three different ways: (1) PE that is office-based (OB; Veterans come to the clinic to meet with the therapist), (2) PE delivered via home-based telehealth (HBT; Veterans stay at home and meet with the therapist using the computer and video cameras), and (3) PE delivered in home, in person (IHIP; the therapist comes to the Veterans' homes for treatment). We will be checking to see if symptoms of PTSD, depression, and anxiety get better (less severe) after the treatment and six months later. We will also see if there are differences in the three ways we will be providing the therapy. We hypothesize that the IHIP approach, compared to the other two approaches, will be more effective at reducing the PTSD symptoms experienced by these Veterans because it will help Veterans attend each session and complete the therapy "homework" assigned by the therapists (such as doing feared activities around the house or the neighborhood). As we have just begun recruitment, we have no major findings to report at this time.					
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## **INTRODUCTION:**

This research study will provide a certain type of exposure therapy, called prolonged exposure therapy (PE) to military Veterans. We will ask 272 Veterans to participate in the study. Our goal is to compare PE conducted in three different ways: (1) PE that is office-based (OB; Veterans come to the clinic to meet with the therapist), (2) PE delivered via home-based telehealth (HBT; Veterans stay at home and meet with the therapist using the computer and video cameras), and (3) PE delivered in home, in person (IHIP; the therapist comes to the Veterans' homes for treatment). We will be checking to see if symptoms of PTSD, depression, and anxiety get better (less severe) after the treatment and six months later. We will also see if there are differences in the three ways we will be providing the therapy. We hypothesize that the IHIP approach, compared to the other two approaches, will be more effective at reducing the PTSD symptoms experienced by these Veterans because it will help Veterans attend each session and complete the therapy "homework" assigned by the therapists (such as doing feared activities around the house or the neighborhood). However, the delivery of IHIP may cost more than the delivery of PE via the other modalities. We expect that the treatment, conducted in all three ways, will reduce the distress caused by PTSD symptoms in most of the participants, which will help to improve the lives of Veterans, their families, and society. The findings of this study will also benefit military Veterans and Active Duty military personnel by investigating new ways for treating PTSD so that the most effective treatments can be made widely available. We will also learn the best ways to manage urgent situations, such as a physical or emotional crisis, that occur when providing treatment in homes and through video technology.

## **BODY:**

Our focus in the past year (30 Sept 2012 – 29 Sept 2013) has been to accomplish many of the tasks outlined in the Statement of Work (SOW) under Tasks 1 and 2. Namely, we attained regulatory approval from HRPO and the VA IRB. We have hired all staff, including the study coordinator (Lucy Moreno), the Project Administrator (Stephanie Wells), and the Research Assistant (Ian Howard). We have also hired our two study assessors (i.e., Independent Clinical Evaluators – ICEs; Kristen Walter and Mary Linges), and we have had them (and other staff) attend two trainings by the developer of the new (DSM-5) Clinician-Administered PTSD Scale (CAPS; Dr. Frank Weathers). We are in talks with the developer of the DSM-5 MINI (general psychiatric diagnoses; Dr. David Sheehan) to include his measure once he has completed it as well. We have also prepared the self-report instrument assessment packets. Additionally, we have hired our study therapists, and they were provided with the four day Prolonged Exposure therapy training for the study (by Drs. Peter Tuerk and Sheila Rauch). The therapists also completed their PE training cases with weekly consultation. Therapists also attend a weekly PE Consultation Team meeting with Dr. Thorp.

We held a meeting for co-investigators and consultants in San Diego to show off-site personnel the facilities in San Diego and to plan details of project procedures. We also conducted monthly phone calls with the entire (national) treatment team (PIs, Co-Is, consultants, study coordinator, statistician, and Project Administrator) and monthly calls with our "sister" project personnel (the DoD StrongStar CPT in-home trial). As noted in our previous quarterly reports [and at the Military Operational Medicine Research Program (MOMRP) Joint Program Committee for Military Operational Medicine (JPC5)

In Progress Review (IPR) meeting on 11 September 2013], we initiated those conversations so that we can share many measures between the sites, with the goal of "comparing apples to apples" when we have final results. We also want to share our successful strategies between sites (such as recruitment methods, telemedicine solutions, etc.) so that we reduce redundancy. We also have weekly in person meetings with our local study personnel.

We have consulted with members of the Home-Based Primary Care team in San Diego, including Co-Investigator Julie Wetherell, to determine best practices for delivering treatment within Veterans' homes. We also had separate meetings with our Co-Investigators, Drs. Peter Shore and Peter Cunningham, about into-home teleconferencing and In-Home, in person visits, respectively. Our foremost concern is safety, and we will have ongoing discussions about ways to maximize safety of Veterans and therapists in all three conditions.

We have obtained our necessary equipment and supplies, and we have reproduced much of the paperwork (e.g., consent forms, questionnaires, handouts, instructions) needed for the project.

We have developed our recruitment materials, including brochures and flyers, and we have discussed the development of internal advertisement for the project (e.g., newsletters, messages on VA TVs). We have determined the primary recruitment sites for the project.

We created an Access Database for study data entry.

As we have just begun recruitment, we have no major findings to report.

On November 1, 2013, we will have our first sessions with pilot subjects to help refine our procedures for recruitment, telephone screening, consent, assessment, the VTC modality, and treatment. On December 12 and 13, 2013, guided by our pilot work, we are having all day trainings on recruitment, screening, assessment (especially determining traumatic events and nuances about PTSD symptom assessment), the treatment protocol, and safety procedures. We will also review study design, regulations concerning the use of human subjects, clinical safety, and confidentiality. Our national team of experts will help guide the study staff about best practices in each of these domains. We plan to be fully operational and streamlined by January 13, 2014.

#### **KEY RESEARCH ACCOMPLISHMENTS:**

We have obtained VA San Diego IRB and R&D Approval to conduct our study (IRB #H130390). HRPO has provided initial approval (and most recent re-approval on October 21, 2013).

We have hired all personnel, and have initiated training with all personnel.

We have consulted with national experts about in-home provision of care (through teleconferencing and in-person).

We have purchased equipment and supplies for the project and prepared paperwork (including recruitment materials).

We created an Access Database for study data entry.

**REPORTABLE OUTCOMES:**

- manuscripts, abstracts, presentations;
  - Dr. Ron Acierno presented progress of our study at the Military Operational Medicine Research Program (MOMRP) Joint Program Committee for Military Operational Medicine (JPC5) In Progress Review (IPR) meeting on 11 September 2013.
- patents and licenses applied for and/or issued;
  - None
- degrees obtained that are supported by this award;
  - None
- development of cell lines, tissue, or serum repositories;
  - N/A
- informatics such as databases and animal models, etc.;
  - An Access Database has been created for use of the present study data entry.
- funding applied for based on work supported by this award;
  - None
- employment or research opportunities applied for and/or received based on experience/training supported by this award.
  - None

**CONCLUSION:**

We have made good progress on the project. We obtained regulatory approvals, hired and trained all personnel, consulted with experts as needed, purchased equipment and supplies, prepared paperwork and recruitment materials, and prepared our database.

**REFERENCES:**

None

**APPENDICES:**

None